CONFIDENTIAL
ATTORNEY-CLIENT PRIVILEGE

Katherine L. WEILAND
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FAX TRANSMISSION

DATE: September 8, 2005

TO: Rosa THOMAS, Esq. FAX NO.: 571-273-0559

FROM: HUESCHEN & SAGE FAX NO.: 269-382-2030

RE: U.S. Serial No. 09/936,676; Christine LIBON, et al.

NO. OF PAGES INCLUDING COVER SHEET: 19

Dear Ms. THOMAS:

To follow up on our conversation of this morning, we provide the following:

Response and Amendment under 37 CFR § 1.111 with two (2) month extension was timely filed under Certificate of Mailing under 37 CFR § 1.8(a) with return postal card receipt on December 1, 2003.

Petition for Revival of an Application for Patent Abandoned Unavoidably under 37 CFR § 1.37(a) was filed on December 14, 2004, a copy of which is enclosed. With the Petition for Revival, a copy of the Response and Amendment of December 1, 2003 and cancelled check No. 72085 for two month extension, a date stamped return postal card receipt indicating receipt of said Response by USPTO mailroom on December 4, 2003, were provided. The USPTO return receipt confirmation of the facsimile transmission of the Petition for Revival of December 14, 2004 is enclosed herewith.

We thank you for your assistance in this matter.

Very truly yours,

THE FIRM OF HUESCHEN AND SAGE

By: Katherine L. Weiland
Katherine L. WEILAND

PTO/SB/61 (11-03)
Approved for use through 07/31/2006. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNAVOIDABLY UNDER 37 CFR 1.137(a)	Docket Number (Optional) PF 98 PCT

First Named Inventor:	Christine LIBON	Art Unit:	1645
Application Number:	09/936,676	Examiner:	Robert Zeman
Filed:	September 14, 2001		

Title: Bacterial Membrane Fractions with Adjuvant Effect

Attention: Office of Petitions
Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

NOTE: If information or assistance is needed in completing this form, please contact Petitions Information at (703)305-9382.

The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the United States Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set for reply in the Office notice or action plus any extensions of time actually obtained.

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION

NOTE: A grantable petition requires the following items:

(1) Petition fee.
(2) Reply and/or issue fee.
(3) Terminal disclaimer with disclaimer fee - required for all utility and plant applications filed before June 8, 1995, and for all design applications; and
(4) Adequate showing of the cause of unavoidable delay.

1. Petition fee

☐ Small entity - fee $ _____ (37 CFR 1.17(l)) Applicant claims small entity status.. See 37 CFR 1.27.

☒ Other than small entity - fee $ 110.00 (37 CFR 1.17(l)).

2. Reply and/or fee

A. The reply and/or fee to the above-noted Office action in the form of

Response & Amendment under 37 CFR § 1.111 with 2 mo. ext fee (identify the type of reply):

☒ has been filed previously on December 1, 2003.
☒ is enclosed herewith.

B. The issue fee of $ _____

☐ has been paid previously on _____.
☐ is enclosed herewith.

PTO/SB/61 (11-03)
Approved for use through 07/31/2006. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNAVOIDABLY UNDER 37 CFR 1.137(a)

Docket Number (Optional): PF 98 PCT SEQ

3. Terminal disclaimer with disclaimer fee

☒ Since this utility/plant application was filed on or after June 8, 1995, no terminal disclaimer is required.

☐ A terminal disclaimer (and disclaimer fee (37 CFR 1.20(d)) of $ for a small entity or $ ther than a small entity) disclaiming the required period of time enclosed herewith (see PTO/SB/63).

4. An adequate showing of the cause of the delay, and that the entire delay in filing the required reply from the due date for the reply until the filing of a grantable petition under 37 CFR 1.137(a) was unavoidable, is enclosed.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorize on PTO-2038.

December 14, 2004
Date

G. PATRICK SAGE
Signature

269 382 0030
Telephone Number

G. PATRICK SAGE
Typed or printed name

37,710
Registration Number, if applicable

500 Columbia Plaza 350 East Michigan Ave.
Address

Kalamazoo, MI 49007
Address

RECEIVED
SEP 19 2005
OFFICE OF PETITIONS

Enclosures: ☒ Fee Payment

☒ Reply

☐ Terminal Disclaimer Form

☐ Additional sheets containing statements establishing unavoidable delay

☒ Response & Amendment , canceled check ,PTO date stamped return post card

CERTIFICATE OF MAILING OR TRANSMISSION [37 CFR 1.8(a)]

I hereby certify that this correspondence is being:

☐ deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

☒ transmitted by facsimile on the date shown below to the United States Patent and Trademark Office at (703) 872-9306.

December 14, 2004
Date

G. PATRICK SAGE
Signature

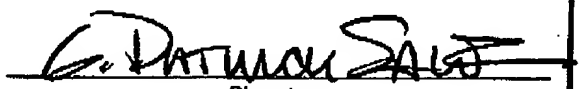
G. PATRICK SAGE
Typed or printed name of person signing certificate

PTO/SB/61 (11-03)
Approved for use through 07/31/2006. OMB 0651-0031
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNAVOIDABLY UNDER 37 CFR 1.137(a)

NOTE: The following showing of the cause of unavoidable delay must be signed by all applicants or by any other party who is presenting statements concerning the cause of delay.

December 14, 2004
Date


Signature

37,710
Registration Number, if applicable

G. PATRICK SAGE
Typed or printed name

(In the space provided below, please explain in detail the reasons for the delay in filing a proper reply)

Response and Amendment under 37 CFR § 1.111 with two (2) month extension were timely filed under Certificate of Mailing under 37 CFR § 1.8(a) with return postal card receipt on December 1, 2003. A copy of said response, date stamped return postal card receipt indicating receipt by USPTO mailroom on December 4, 2003 and cancelled check no. 72085 for two (2) month extension are enclosed. As this abandonment was not only unavoidable but also the result of USPTO error, reimbursement of the entire petition fee is hereby respect fully solicited.

(Please attach additional sheets if additional space is needed.)

PTO/SB/17 (10-03)
Approved for use through 07/31/2006. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2005

Effective 10/01/2004. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) $110.00

Complete if Known	
Application Number	09/936,676
Filing Date	September 14, 2001
First Named Inventor	Christine LIBON
Examiner Name	Robert ZEMAN
Art Unit	1645
Attorney Docket No.	PF 98 PCT SEQ

RECEIVED CENTRAL FAX CENTER SEP 08 2005

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 08-3220

Deposit Account Name: The Firm of Hueschen and Sage

The Director is authorized to: *(check all that apply)*

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☐ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	790	2001	395	Utility filing fee	
1002	350	2002	175	Design filing fee	
1003	550	2003	275	Plant filing fee	
1004	790	2004	395	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND

	Extra Claims			Fee from below	Fee Paid
Total Claims		-20** =	0	X =	0.00
Independent Claims		- 3** =	0	X =	0.00
Multiple Dependent				=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	88	2201	44	Independent claims in excess of 3
1203	300	2203	150	Multiple dependent claim, if not paid
1204	88	2204	44	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) $0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

RECEIVED SEP 19 2005 OFFICE OF PETITIONS

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non - English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	430	2252	215	Extension for reply within second month	
1253	980	2253	490	Extension for reply within third month	
1254	1,530	2254	765	Extension for reply within fourth month	
1255	2,080	2255	1,040	Extension for reply within fifth month	
1401	340	2401	170	Notice of Appeal	
1402	340	2402	170	Filing a brief in support of an appeal	
1403	300	2403	150	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	110.00
1453	1,370	2453	685	Petition to revive - unintentional	
1501	1,370	2501	685	Utility issue fee (or reissue)	
1502	490	2502	245	Design issue fee	
1503	660	2503	330	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR § 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Statement	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	790	2809	395	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	790	2810	395	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	790	2801	395	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) $110.00

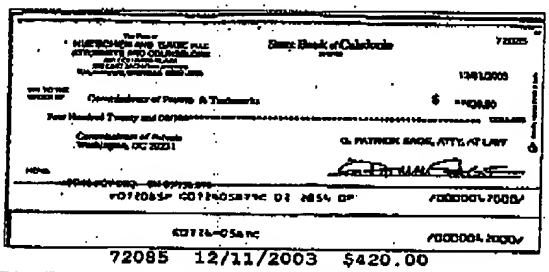
SUBMITTED BY				Complete (if applicable)	
Name (Print/Type)	G. PATRICK SAGE	Registration No. (Attorney/Agent)	37,710	Telephone	269 382 0030
Signature	G. Patrick Sage			Date	December 14, 2004

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

State Bank of Caledonia



72085 12/11/2003 $420.00

Applicants Christine LIBON, et al.
Title BACTERIAL MEMBRANE FRACTIONS WITH ADJUVANT EFFECT
Serial No 09/936,676
Filing Date September 14, 2001
Art Unit 1645
Examiner Robert A. ZEMAN, Esq.

The USPTO mailroom stamp affixed hereon will acknowledge receipt by Certificate of Mailing filing procedure of: Response and Amendment, Listing of Claims, Extension Fee for two (2) month's extension, return postal card receipt.

PF 98 PCT SEQ / December 1, 2003 / gpsage

PF 98 PCT SEQ

* * * * *

Applicant	:	Christine LIBON, Nathalie CORVAIA, Thien Ngoc N'GUYEN, Alain BECK and Jean-Yves BONNEFOY
Serial No.	:	09/936,676
Filed	:	September 14, 2001
Title	:	Bacterial Membrane Fractions with Adjuvant Effect
Art Unit	:	1645
Examiner	:	Robert A. ZEMAN, Esq.

* * * * *

Honorable Commissioner of Patents and Trademarks

Washington, D.C. 20231

RESPONSE AND AMENDMENT UNDER 37 CFR § 1.111

Sir:

Responsive to the Office action, dated July 1, 2003, **as to which the period for response has been extended by two (2) months by payment of the appropriate fee,** kindly amend as follows:

IN THE CLAIMS:

See Listing of Claims attached hereto which will replace all prior versions of claims in the application.

Claims 34, 38, 41-43, 49, 50 and 72: Presently amended

Claims 35, 39, 40, 44-48 and 52-54: Canceled

REMARKS

The applicants acknowledge the Office Action of July 1, 2003, with appreciation. To begin, the Office acknowledges Applicant's election of Group I, in Paper No. 5. The Office indicates the election as filed will be treated as an election *without traverse*. By designating the subject matter outside the elected group as being merely withdrawn pending notification of allowable subject matter, the applicants distinctly and affirmatively point out subject matter which they assert, upon examination will be found a part of the claimed invention. The applicants reassert their right to rejoin non-elected claims upon the identification of allowable subject matter.

Claims 34-72 are pending in the Application, of those, Claim 36, 37, and 55-71 were withdrawn from consideration. Claims 34, 35, 38-54 and 72 were rejected by the Office under 35 U.S.C §112, second paragraph, as being indefinite for failing to claim with particularity. Claims 34 and 72 were considered indefinite for use of the term "orienting". Claims 34 and 72 are presently amended to substitute the term "inducing", as kindly suggested by the Office. Additionally, Claims 34 and 72 are considered vague and indefinite for the use of the phrase "in which the Th1 response is close to or greater than the Th2 type response". Applicants note that the language "close to" finds Specificational support on page 3, lines 35-39. The language "or greater than" has been removed from the presently amended Claims 34 and 72. Additionally, Claims 34 and 72 were amended to further limit the instant invention to the use of a crude membrane fraction obtained from *K. pneumoniae* by a process of preparation, as disclosed in the Specification, which is mixed with an antigen or hapten to elicit the desired immune response.

Claim 38 was rejected for improper Markush language. The claim has been amended to conform to proper language, as kindly suggested by the Office. Similarly, Claim 51 was amended to define a proper Markush group.

Claim 41 was considered indefinite for the use of the term "capable of". Similarly, Claim 42 was considered indefinite for use of the term "derived from". Objectionable language has been removed from Claims 41 and 42, thereby providing the requested definition.

Claim 43 and Claim 48 were rejected for improper use of the language "genetic recombination". Applicants submit the language "recombinant technologies" as a more appropriate term. Using recombinant technologies for heterologous protein expression to form proteinaceous complexes finds Specificational support on page 10, lines 16-29.

Claim 49 is rejected for the language "carry the membrane fraction...in a form...which makes it possible to enhance..." Applicants have amended the claim and removed the objectional language, "makes it possible". Applicants submit that these amendments provide the requested definition.

Moving on to the prior art rejections, the Office rejects claims 34, 38-40, 44, 48 and 72 under 35 USC §102(b) as being anticipated by Rauly, et al., (Research in Immunology, Vol. 149 No. 1, pg.99, January 1998) which discloses the use of a homogeneous preparation of recombinant *K. pneumoniae* P40 protein as an immunopotentiator. When coupled to a B-cell epitope derived from RSV, the resulting complex induces a mixed Th1/Th2 response when administered to animals. The instant invention as claimed limits the Th1 type response to be close to the Th2 response, as defined in the Specification. Applicants acknowledge Rauly, et al. decribes a mixed immune response following immunization with P40-hapten preparations. However, there is no disclosure of the magnitude of the Th1 response of the mixed response obtained using recombinant P40. Applicants invite the Office to consider the disclosure of the cited Binz, et al., (US Patent 6,197,929; column 10, lines 36-47, Table 4) wherein the mixed immune response following immunization with the P40-hapten is characterized in detail with respect to the antibody isotypes. The mixed immune response elicited following immunization with the P40-hapten is one in which the Th1 response, particularly IgG2a and IgG3 isotypes, is significantly less than the Th2 response, particularly IgG1 and IgG2b isotypes. Applicants submit that the Office has not made an adequate demonstration of anticipation or provided a demonstration that Rauly, et al. suggests the instant invention. Applicants have demonstrated that immunization with the instant crude membrane fraction, FMKp, elicites a preferred immune response, one in which the Th1 response is close to the Th2 response. Such Th1/Th2 profile having a Th1 specific response close to the Th2 response is desired particularly to avoid an essentially Th2 response which poses problems in subjects with allergic predisposition (pg. 2, lines 15-29 of the Specification).

Applicants also note that Rauly, et al. adeptly demonstrates carrier-related differences in the immune response generated against the same antigen or hapten. The rP40-G1' conjugate generated a mixed Th1/Th2 repsonse, in contrast to tetanus toxoid-G1' conjugate, which induced a Th2-like type of response. Claim 34 and Claim 72 have presently been amended to further limit the instant invention to the use of a crude membrane extract from *K. pneumoniae,* FMKp, obtained by a defined process of preparation, to be used as a carrier to elicit the claimed immune response. The crude membrane preparation is materially distinct from a purified, recombinant P40 protein preparation. As demonstrated by Rauly, et al. differences in the carrier protein affect the immune response directed to a particular antigen or hapten. Consequently, the reference may not be relied upon for the teaching that *K. pneumoniae* membrane carriers can be expected to induce uniform responses, much less the instant, mixed immune response. The reference does not suggest the performance of the crude membrane fraction, FMKp, when mixed with an antigen or hapten, would result in the claimed immune response. Based upon these analyses, Applicants submit that the instant invention is not anticipated, nor made obvious by the disclosure of Rauly, et al.

The Office goes on to reject Claims 34, 38-41, 43-54, 48-49 and 72 under 35 USC §102(e) as being anticipated by Binz, et al., (US Patent 6,197,929). The reference also discloses the use of recombinant *K. pneumoniae* P40 protein as an immunopotentiator, as well as *K. pneumoniae* protein that was purified through chromatographic techniques to obtain a homogeneous P40 preparation, free from other contaminating membrane components. The immune response was evaluated following immunization with covalent P40/hapten complexes (P40ext). The Office draws attention to a Th1 response, which is generated in animals, and is exemplified by the production of a highly quantitative delayed hypersensitivity response and macrophage activation. Applicants acknowledge these analyses and further consider the indepth analysis of the antibody isotype distribution that defines a Th1 type response and a Th2 type response following P40 immunization. The reference indicates that the titer of Th1 isotype antibodies, particularly IgG2a and IgG3, is much lower than the titer of Th2 isotype antibodies, particularly IgG1 and IgG2b and IgE (column 10, lines 36-47, Table 4). This is in stark contrast to the instant invention, as recited in Claims 34 and 72, which results in a "mixed Th1/Th2 response directed against an antigen or hapten, in which response the Th1 response is close to the Th2 response" following immunization with a mixture of FMKp/hapten. The Office has not made a *prima facie* demonstration that one skilled

in the art would expect the capacity of the instant crude membrane fraction to induce the claimed response which is characterized by the distinguishing Th1/Th2 mixed response, wherein the Th1 response is close to the Th2 response. Therefore, Applicants submit that the instant invention is not anticipated, nor made obvious, by the disclosure of Binz, et al., (US Patent 6,197,929).

Finally, the applicants note again that the references cited by the Office pertain to the use of specifically P40 protein preparations which are recombinantly expressed and purified or are purified to homogeneity from *K. pneumoniae* using extensive chromatographic techniques. These preparations are materially distinct from the composition of the crude membrane preparation of the instant invention. Neither reference suggests the performance of the claimed crude membrane preparation as an immunopotentiator. The former Claims 34 and 72 are presently limited to immunization with the crude membrane fraction, mixed with an antigen or hapten, to generate a preferred type of immune response, directed against the antigen or hapten. The cited references disclose only P40 protein preparations that are covalently coupled or combined with an antigen or hapten, which are capable of inducing a mixed Th1/Th2 response. Additionally, neither reference demonstrates, nor suggests, the claimed immune response, one in which the Th1 response is close to the Th2 response, as defined in the Specification of the instant invention, can be obtained using P40 protein as a carrier.

Applicants submit that these cited references actually sustain the novelty of the instant invention. Rauly, et al. demonstates that different carrier proteins have a differential affect on the type of immune response elicited to a singular antigen or hapten. Considering Binz, et al. the immune response elicited by immunization with purified P40 teaches away from the claimed mixed response of the instant invention. Neither reference suggests or anticipates the performance of the crude membrane fraction, FMKp, mixed with antigen or hapten, could elicit the preferred immune response, in which the Th1 response is close to the Th2 response. In light of these remarks, reconsideration and withdrawal of the prior art rejection is respectfully solicited.

* * * * *

Accordingly, entry of the present amendment, reconsideration of all grounds of rejection, withdrawl thereof and passage of this application to issue are all thereby respectfully solicited.

It should be apparent that the undersigned attorney has made an earnest effort to place this application into condition for immediate allowance. If he can be of assistance to the Examiner in the elimination of any possibly-outstanding insignificant impediment to an immediate allowance, the Examiner is invited to call him at his below-listed number for such purpose.

Allowance is solicited.

Respectfully submitted,
THE FIRM OF HUESCHEN AND SAGE

By: _____
G. PATRICK SAGE, Attorney #37,710

Dated: 12/1/2003
Customer No.: 25,666
500 Columbia Plaza
350 East Michigan Ave.
Kalamazoo, MI 49007-3856
(269) 382-0030
GPS/KLW

Enclosure: Listing of Claims, Extension Fee (Two months) $420.00 and Postal Card Receipt

*****

THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY FURTHER OR ADDITIONAL FEES WHICH MAY BE REQUIRED (DUE TO OMISSION, DEFICIENCY, OR OTHERWISE), OR TO CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 08,3220.

Listing of Claims

Claim 34. (presently amended): A method of ~~orienting~~ inducing an immune response toward a ~~Th1-type and/or~~ mixed Th1/Th2 type response directed against an antigen or hapten, in which response the Th1 response is close to ~~or greater than~~ the Th2 response, comprising the step of administering to a living animal body an amount of a *Klebsiella pneumoniae* membrane fraction ~~combined~~ admixed with the antigen or hapten, which is effective in ~~orienting~~ inducing the immune response toward a ~~Th1 type and/or~~ mixed Th1/Th2 type response directed against the antigen or hapten, in which response the Th1 response is close to ~~or greater than~~ the Th2 type response, and wherein said *Klebsiella pneumoniae* membrane fraction is obtained by a process of preparation comprising a step of lysing the *Klebsiella pneumoniae* bacteria after culture and a step of separating the fraction comprising the membranes from the total lysate obtained after the step of lysing.

Claim 35. (canceled)

Claim 36. (withdrawn) The use of Claim 34, wherein the membrane fraction is prepared by a method comprising the following steps:

a) culture of the bacteria in a culture medium allowing their growth followed by centrifugation of the culture;
b) where appropriate, deactivation of the lytic enzymes of the bacterial pellet obtained in step a), followed by centrifugation of the suspension obtained;
c) extraction and removal of nonmembrane proteins and of nucleic acids from the pellet obtained in step a) or b) by at least one cycle of washing the pellet in an extraction solution;
d) digestion of the membrane pellet obtained in step c) in the presence of protease enzymes, followed by centrifugation;
e) at least one cycle of washing of the pellet obtained in step d) in physiological saline and/or in distilled water; and
f) ultrasonication of the pellet obtained in step e).

Claim 37. (withdrawn) The use of Claim 34, wherein the membrane fraction is prepared by a method comprising the following steps:

a) culture of the bacteria in a culture medium allowing their growth, followed, where appropriate, by centrifugation;

b) freezing of the culture medium or of the pellet obtained in step a) followed by thawing and drying of the cells;

c) removal, by means of a DNase, of the nucleic acids from the dry cells obtained in step b) which have been resuspended;

d) grinding of the cells obtained in step c) and clarification of the suspension obtained;

e) precipitation, in an acid medium, of the suspension obtained in step d) and removal of the pellet;

f) neutralization of the supernatant obtained in step e) containing the membrane suspension, followed by dialysis and concentration of the membrane suspension; and

g) sterilization of the concentrated membrane suspension obtained in step f).

Claim 38. (presently amended): The method of claim 34, wherein the antigen or hapten is ~~chosen from the~~ an antigen[s] or hapten[s] specific to an infectious agent or ~~from~~ the antigen[s] is associated with tumor cells.

Claim 39. (canceled)

Claim 40. (canceled)

Claim 41. (presently amended): The method of Claim 34, wherein the antigen or hapten is covalently coupled with a supporting peptide to form a complex ~~capable of specifically binding~~ that binds to mammalian serum albumin.

Claim 42. (presently amended): The method of Claim 41, wherein the supporting peptide is a peptide fragment ~~derived from~~ of the streptococcal G protein.

Claim 43. (presently amended) The method of claim 41, wherein the complex is prepared by ~~genetic recombination~~ recombinant technology.

Claim 44. (canceled)

Claim 45. (canceled)

Claim 46. (canceled)

Claim 47. (canceled)

Claim 48. (canceled)

Claim 49. (presently amended): The pharmaceutical composition of Claim 72, wherein the composition comprises an agent which ~~makes it possible to carry~~ carries the membrane fraction associated with the antigen, hapten or complex, in [a] the form ~~which makes it possible to~~ of an emulsion or encapsulated particle, thereby ~~enhance~~ enhancing its stability and /or its immunogenicity.

Claim 50. (previously presented): The pharmaceutical composition of Claim 49, wherein the agent is an oil-in-water or water-in-oil type emulsion.

Claim 51. (presently amended): The pharmaceutical composition of Claim 49, wherein the agent is a ~~particle of the~~ liposome, a microsphere or a nanosphere ~~type or any type of structure allowing the encapsulation and the presentation in particulate form of the membrane fraction associated with the antigen, hapten, or complex~~.

Claim 52. (canceled)

Claim 53. (canceled)

Claim 54. (canceled)

Claim 55. (withdrawn) The use of Claim 34 for the preparation of a pharmaceutical composition intended for the prevention or treatment of infectious diseases or cancers.

Claim 56. (withdrawn) The use of Claim 55, wherein the infectious disease is of viral, bacterial, fungal or parasitic origin.

Claim 57. (withdrawn) The use of Claim 56 for the preparation of a pharmaceutical composition intended for the prevention or treatment of paramyxovirus infections.

Claim 58. (withdrawn) The use of Claim 57, wherein the paramyxovirus is a respiratory syncytial virus.

Claim 59. (withdrawn) The use of Claim 58, wherein the antigen associated with the membrane fraction comprises the peptide G2Na of SEQ ID No. 4 or one of its homologs whose sequence exhibits a degree of identity of at least 80% with SEQ ID No. 4.

Claim 60. (withdrawn) The use of Claim 59, wherein the peptide G2Na or one of its homologs is covalently coupled with a C-terminal fragment (BB) of the streptococcal G protein to form a complex capable of binding to mammalian serum albumin.

Claim 61. (withdrawn) The use of Claim 57, wherein the paramyxovirus is a parainfluenzae virus.

Claim 62. (withdrawn) A pharmaceutical composition comprising a membrane fraction prepared by the method of Claim 36 and an antigen or hapten associated with the membrane fraction.

Claim 63. (withdrawn) A pharmaceutical composition comprising a membrane fraction prepared by the method of Claim 37 and an antigen or hapten associated with the membrane fraction.

Claim 64. (withdrawn) The pharmaceutical composition of Claim 62, wherein the antigen is chosen from paramyxovirus peptide fragments.

Claim 65. (withdrawn) The pharmaceutical composition of Claim 63, wherein the antigen is chosen from paramyxovirus peptide fragments.

Claim 66. (withdrawn) The pharmaceutical composition of Claim 64, wherein the paramyxovirus is a respiratory syncytial virus or a parainfluenzae virus.

Claim 67. (withdrawn) The pharmaceutical composition of Claim 65, wherein the paramyxovirus is a respiratory syncytial virus or a parainfluenzae virus.

Claim 68. (withdrawn) The pharmaceutical composition of Claim 66, wherein the antigen associated with the membrane fraction comprises the peptide G2Na of

SEQ ID No. 4 of the respiratory syncytial virus or a peptide whose sequence exhibits a degree of identity of at least 80% with SEQ ID No. 4.

Claim 69. (withdrawn) The pharmaceutical composition of Claim 67, wherein the antigen associated with the membrane fraction comprises the peptide G2Na of SEQ ID No. 4 of the respiratory syncytial virus or a peptide whose sequence exhibits a degree of identity of at least 80% with SEQ ID No. 4.

Claim 70. (withdrawn) The pharmaceutical composition of Claim 68, wherein the peptide G2Na, or one of it homologs, is covalently coupled with a C-terminal fragment (BB) of the streptococcal G protein to form a complex capable of binding to mammalian serum albumin.

Claim 71. (withdrawn) The pharmaceutical composition of Claim 69, wherein the peptide G2Na, or one of it homologs, is covalently coupled with a C-terminal fragment (BB) of the streptococcal G protein to form a complex capable of binding to mammalian serum albumin.

Claim 72. (presently amended): A pharmaceutical composition comprising a *Klebsiella pneumoniae* membrane fraction ~~combined~~ admixed with an antigen or hapten, which is effective in ~~orienting~~ inducing an immune response toward a ~~Th1 type and/or~~ mixed Th1/Th2 type response directed against the antigen or hapten, in which response the Th1 response is close to ~~or greater than~~ the Th2 type response, with a pharmaceutically acceptable carrier, diluent and/or additive, and wherein said *Klebsiella pneumoniae* membrane fraction is obtained by a process of preparation comprising a step of lysing the *Klebsiella pneumoniae* bacteria after culture and a step of separating the fraction comprising the membranes from the total lysate obtained after the step of lysing.

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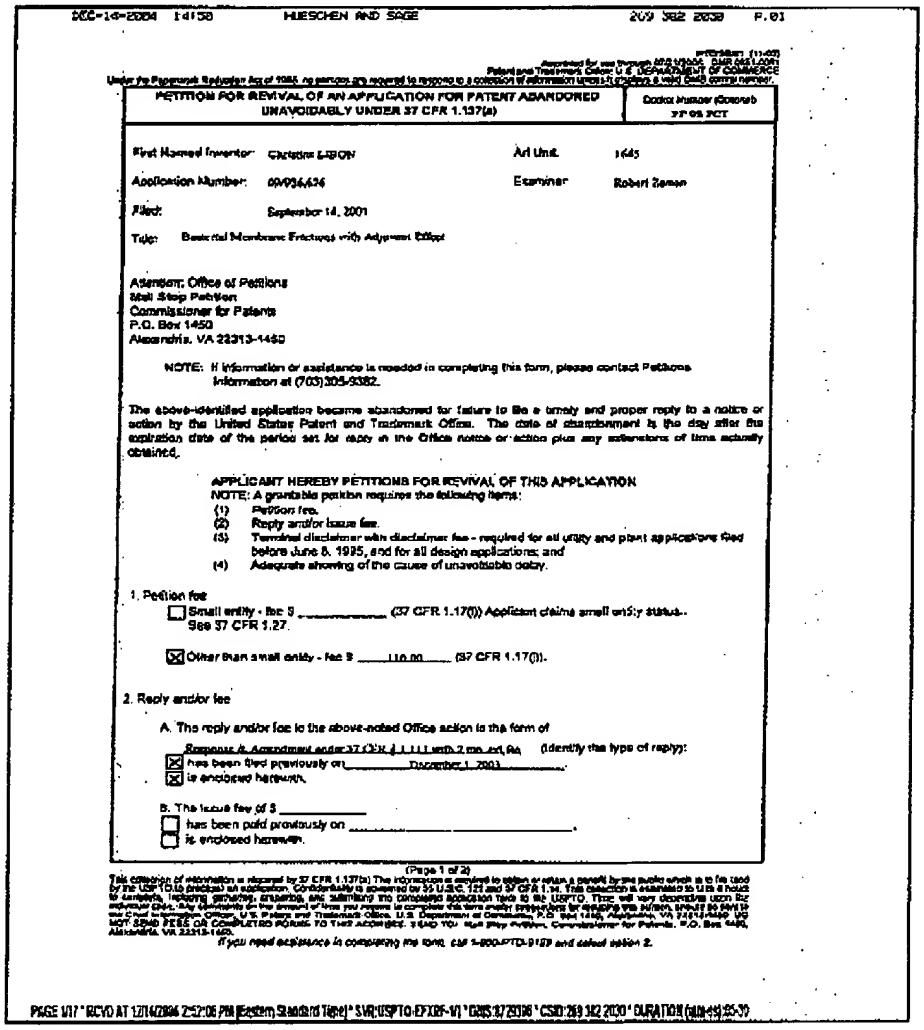

DEC-14-2004 14:58 HUESCHEN AND SAGE 269 382 2030 P.01

PETITION FOR REVIVAL OF AN APPLICATION FOR PATENT ABANDONED UNAVOIDABLY UNDER 37 CFR 1.137(a)

Docket Number (Optional): 27 05 PCT

First Named Inventor: Christine LISON
Art Unit: 1645
Application Number: 09/936,636
Examiner: Robert Zeman
Filed: September 14, 2001
Title: Bacterial Membrane Fractions with Adjuvant Effect

Attention: Office of Petitions
Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

NOTE: If information or assistance is needed in completing this form, please contact Petitions Information at (703)305-9282.

The above-identified application became abandoned for failure to file a timely and proper reply to a notice or action by the United States Patent and Trademark Office. The date of abandonment is the day after the expiration date of the period set for reply in the Office notice or action plus any extensions of time actually obtained.

APPLICANT HEREBY PETITIONS FOR REVIVAL OF THIS APPLICATION
NOTE: A grantable petition requires the following items:
(1) Petition fee.
(2) Reply and/or issue fee.
(3) Terminal disclaimer with disclaimer fee - required for all utility and plant applications filed before June 8, 1995, and for all design applications; and
(4) Adequate showing of the cause of unavoidable delay.

1. Petition fee
☐ Small entity - fee $ _____ (37 CFR 1.17(l)) Applicant claims small entity status. See 37 CFR 1.27.
☒ Other than small entity - fee $ 110.00 (37 CFR 1.17(l)).

2. Reply and/or fee
A. The reply and/or fee to the above-noted Office action in the form of
Response & Amendment under 37 C.F.R. § 1.111 with 2 mo. ext. fee (identify the type of reply):
☒ has been filed previously on December 1, 2003.
☒ is enclosed herewith.
B. The issue fee of $ _____
☐ has been paid previously on _____.
☐ is enclosed herewith.

(Page 1 of 2)

This collection of information is required by 37 CFR 1.137(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.
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